NICE National Institute for Health and Care Excellence

NICE approach to point of care tests for antimicrobials

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NICE Scientific Advice

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Introduction to NICE & Health Technology Assessment (HTA)

The background: why NICE was set up

- Established in 1999
- Aim: to reduce variation in the availability and quality of treatments and care (the so called ‘postcode lottery’)
- To resolve uncertainty about which medicines and treatments work best and which represent best value for money for the NHS

What is NICE?

An independent institute that identifies how to:

- prevent, diagnose and treat disease and ill health in most effective ways
- reduce inequalities and variation
- ensure quality and value for money for the NHS

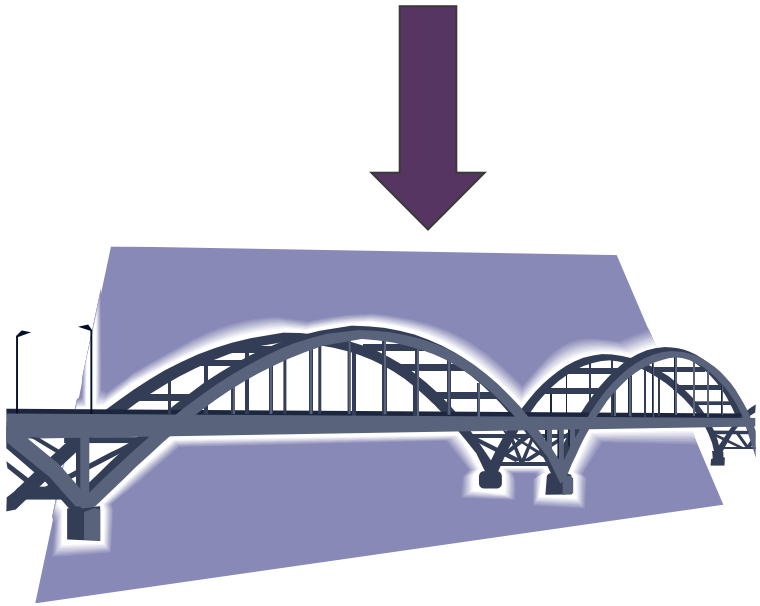
Opportunity cost

NICE: Improving outcomes for people

What is Health Technology Assessment (HTA) ?

Product

Evidence



Market

Policy-making

Evidence-based
Includes the efficient allocation of health care resources

Difficulties faced by medtech/diagnostic companies

- Complex decision-making processes
- Many stakeholders – may delay change
- Difficulty getting peer reviewed research
- Competing with long-established practice – may act as a block to change
- Funding

Scarce resources = difficult decisions

HTA

Health Technology Assessment

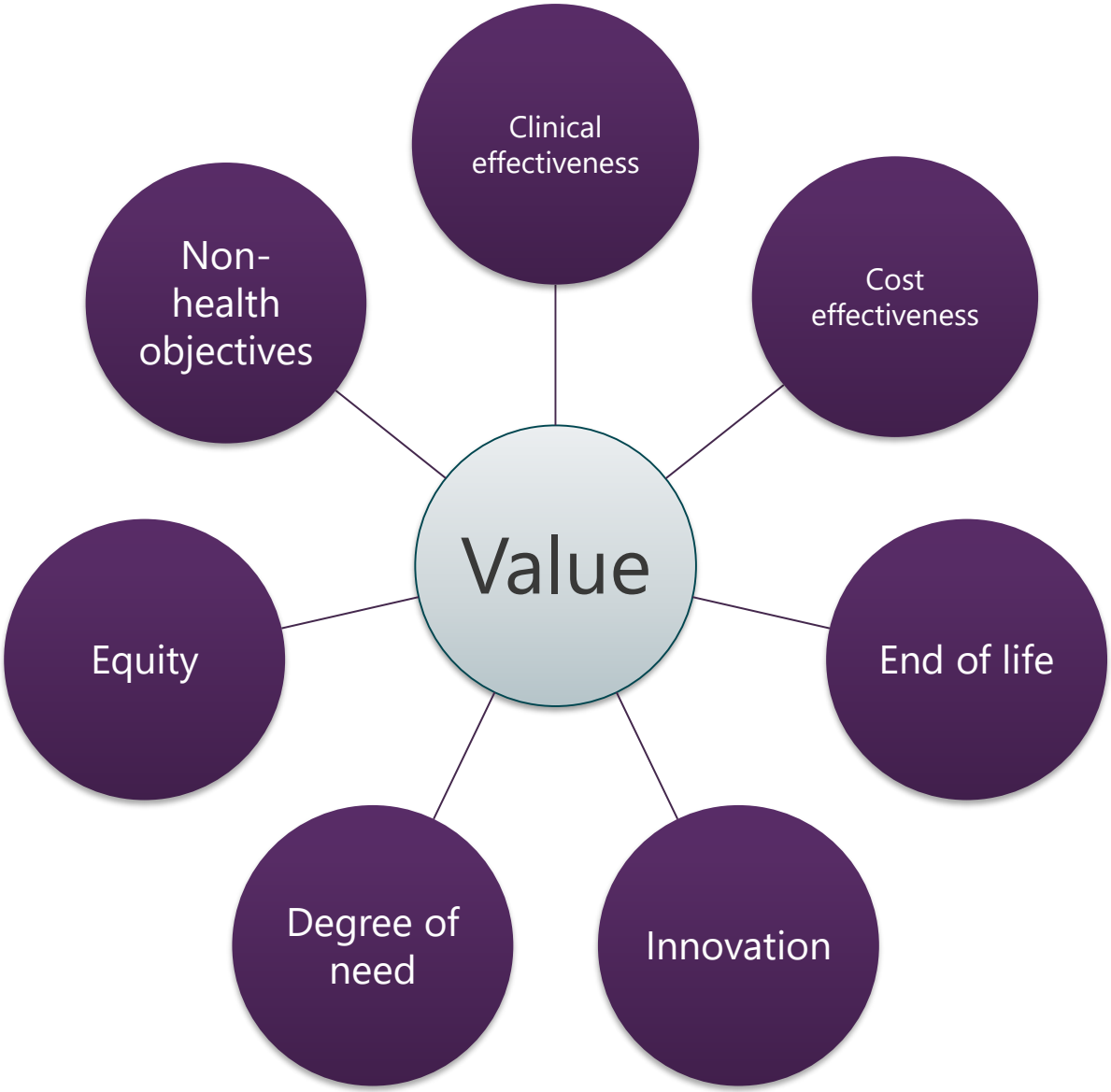
Triple E of Healthcare Technologies

Does it work in clinical trials?

Does it work in clinical practice?

Does it contribute to the efficient use of resources?

What does NICE value?



Regulatory perspective

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Efficacy
Safety

MHRA
Regulating Medicines and Medical Devices

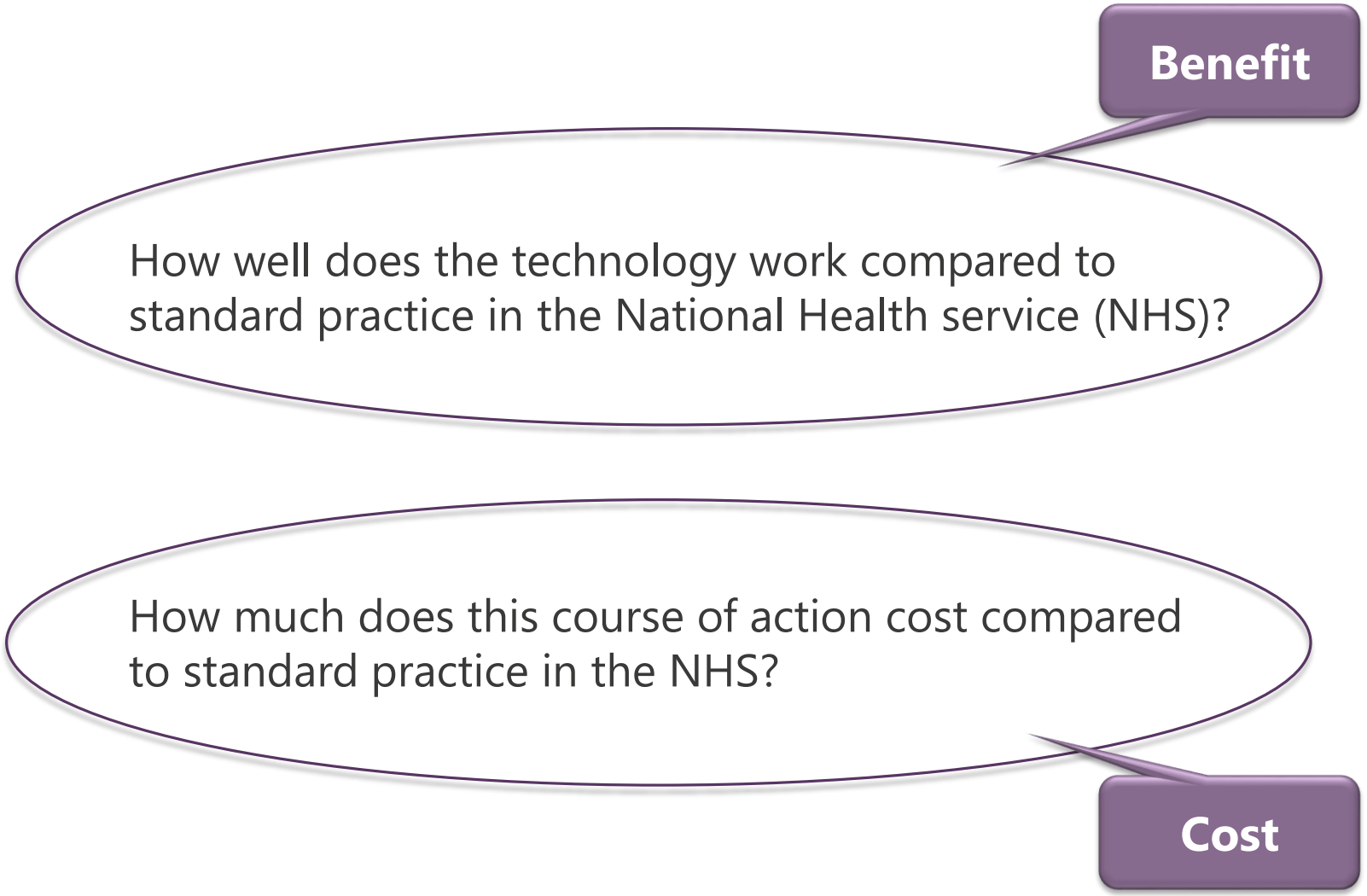
HTA perspective

NICE

Clinical effectiveness
Cost effectiveness

The same evidence can lead to different decisions

Two key questions asked by NICE



AMR Point of Care tests and NICE

Prescribing policy in the NHS

https://www.nice.org.uk/Media/Default/About/what-we-do/Into-practice/measuring-uptake/NICEimpact-antimicrobial-resistance.pdf

AMR at NICE

Common Infections Guidance from NHS England:

- Rapid guidance within an ongoing programme to promote appropriate antimicrobial use

NICE Guidance:

- Antimicrobial stewardship: changing risk-related behaviours in the general population (NG63)
- Antimicrobial stewardship: systems and processes for effective antimicrobial medicine use (NG15)
- Antimicrobial stewardship (QS121)

NG15 – relevant sections

1.1.22 Ensure that laboratory testing and the order in which the susceptibility of organisms to antimicrobials is reported is in line with: national and local treatment guidelines, the choice of antimicrobial in the local formulary, the priorities of medicines management and antimicrobial stewardship teams.

1.1.25 When deciding whether or not to prescribe an antimicrobial, take into account the risk of antimicrobial resistance for individual patients and the population as a whole.

1.1.26 When prescribing any antimicrobial, undertake a clinical assessment and document the clinical diagnosis (including symptoms) in the patient's record and clinical management plan.

1.1.27 For patients in hospital who have suspected infections, take microbiological samples before prescribing an antimicrobial and review the prescription when the results are available.

NG15 – relevant sections

1.1.28 For patients in primary care who have recurrent or persistent infections, consider taking microbiological samples when prescribing an antimicrobial and review the prescription when the results are available.

1.1.29 For patients who have non-severe infections, consider taking microbiological samples before making a decision about prescribing an antimicrobial, providing it is safe to withhold treatment until the results are available.

1.1.30 Consider point-of-care testing in primary care for patients with suspected lower respiratory tract infections as described in the NICE guideline on pneumonia in adults.

Previous NICE publications related to AMR PoC

3 MIBs:

Alere Afinion CRP for C-reactive protein testing in primary care [MIB81]

QuikRead go for C-reactive protein testing in primary care [MIB78]

Xpert Carba-R to identify people carrying carbapenemase-producing organisms [MIB52]

All 2016

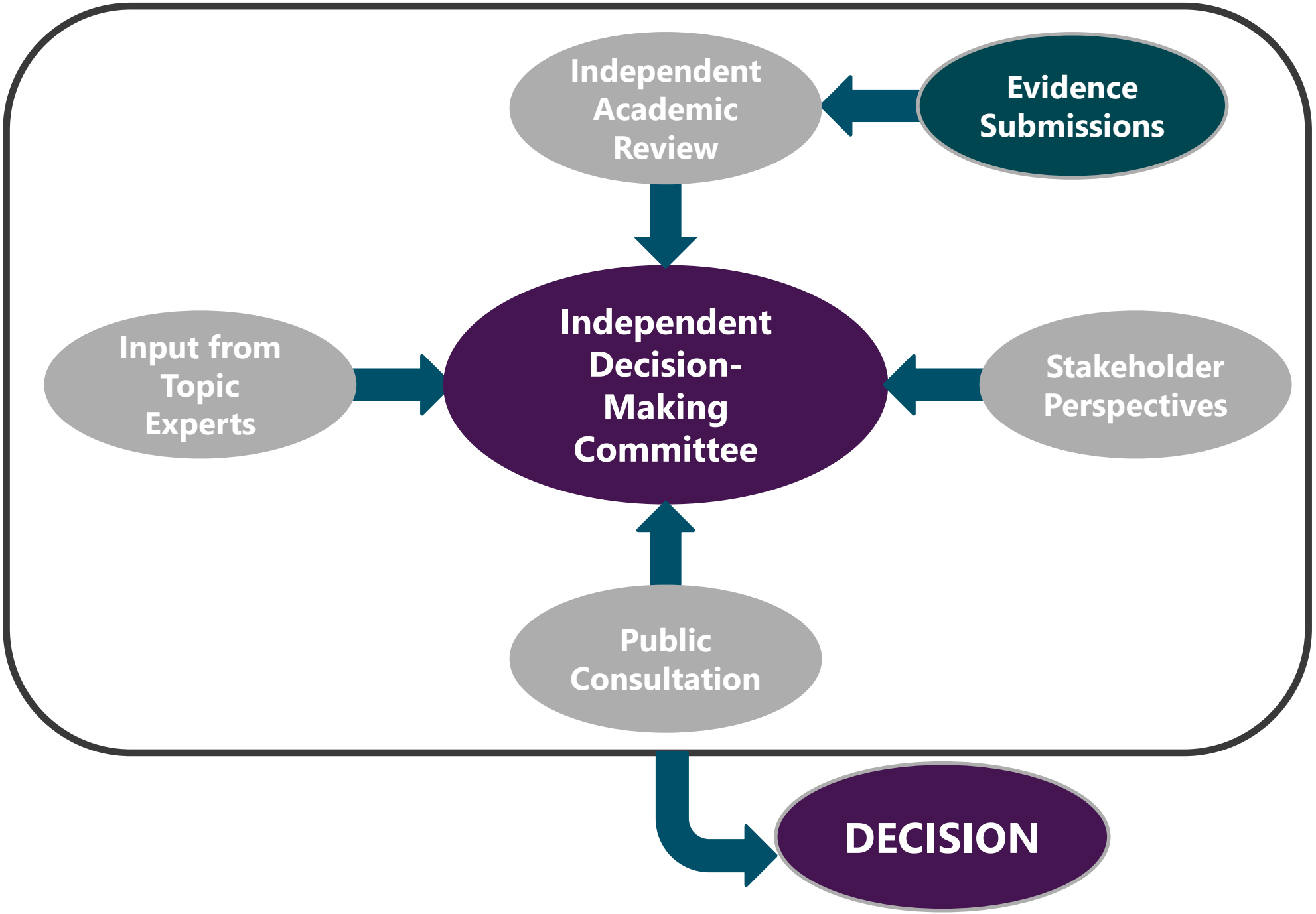
1 DG

Procalcitonin testing for diagnosing and monitoring sepsis (ADVIA Centaur BRAHMS PCT assay, BRAHMS PCT Sensitive Kryptor assay, Elecsys BRAHMS PCT assay, LIAISON BRAHMS PCT assay and VIDAS BRAHMS PCT assay) [DG18]

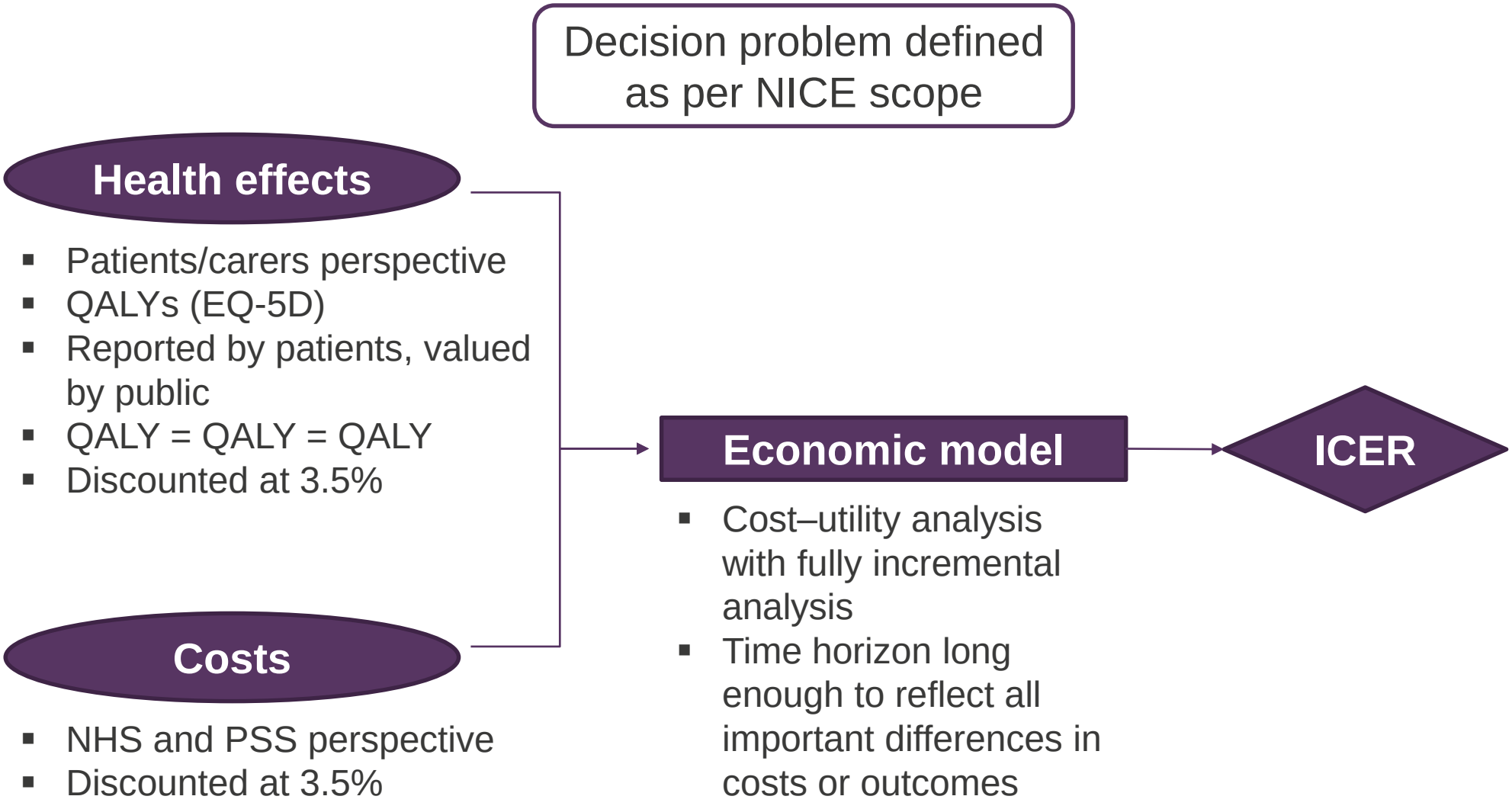
October 2015

NOT ENOUGH EVIDENCE FOR GUIDANCE

Decision making


Independent Academic Review
Evidence Submissions
Input from Topic Experts
Independent Decision-Making Committee
Stakeholder Perspectives
Public Consultation
DECISION

Summary of the NICE reference case



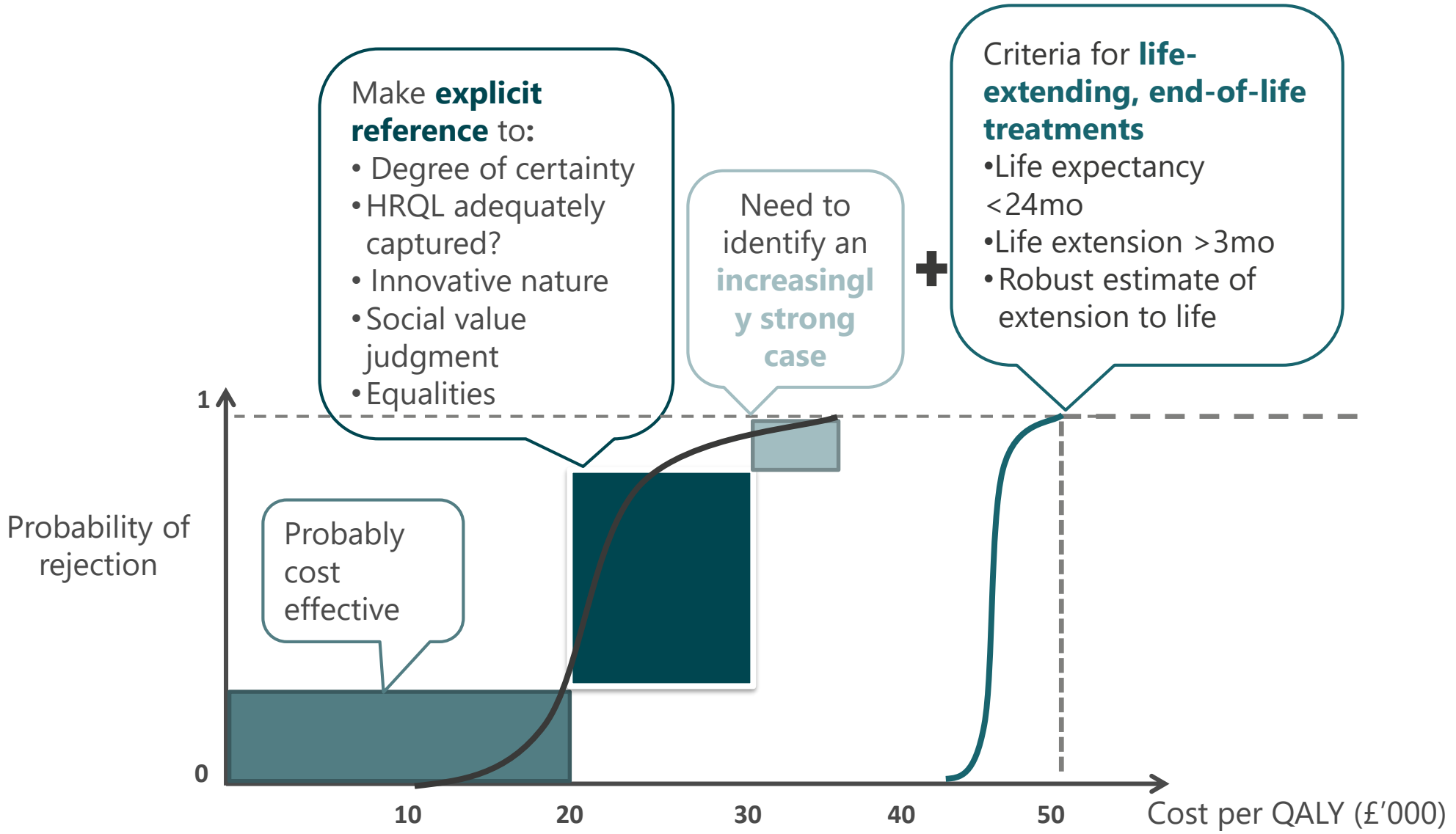
Economic evaluation

$$\text{ICER} = \frac{\text{difference in cost (current treatment vs new treatment)}}{\text{difference in effect (current treatment vs new treatment)}}$$

I	Incremental: extra, additional
C	Cost: how much do we have to pay?
E	Effectiveness: what do we get (in QALYs)?
R	Ratio: unit per unit (e.g. km/h) – we use cost per QALY

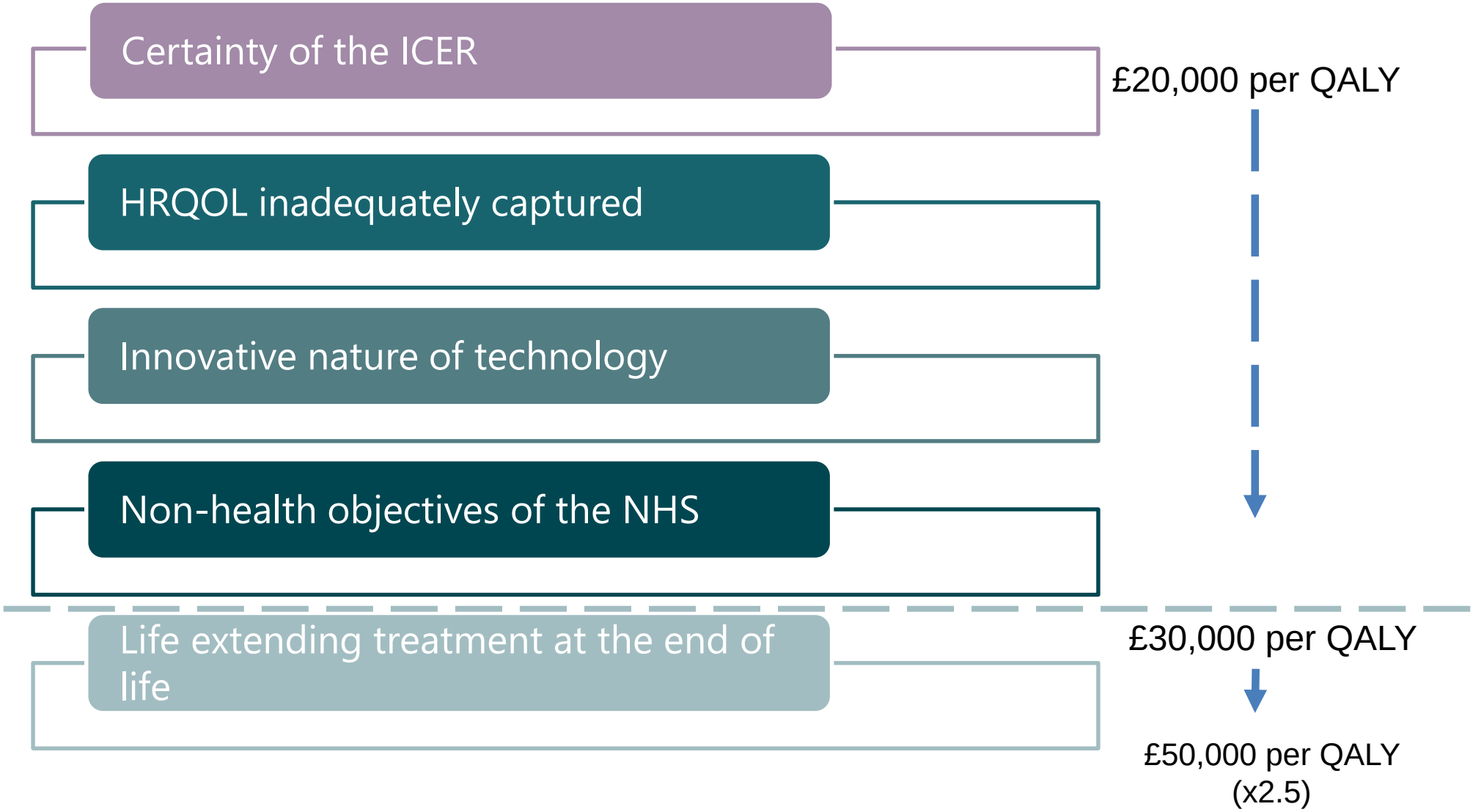
Does the value of health gain justify the additional resources required for the new treatment compared to the current treatment?

Committee decision making



Why doesn’t NICE have a fixed threshold?

Decision-making approach



Understanding value

What is a value proposition?

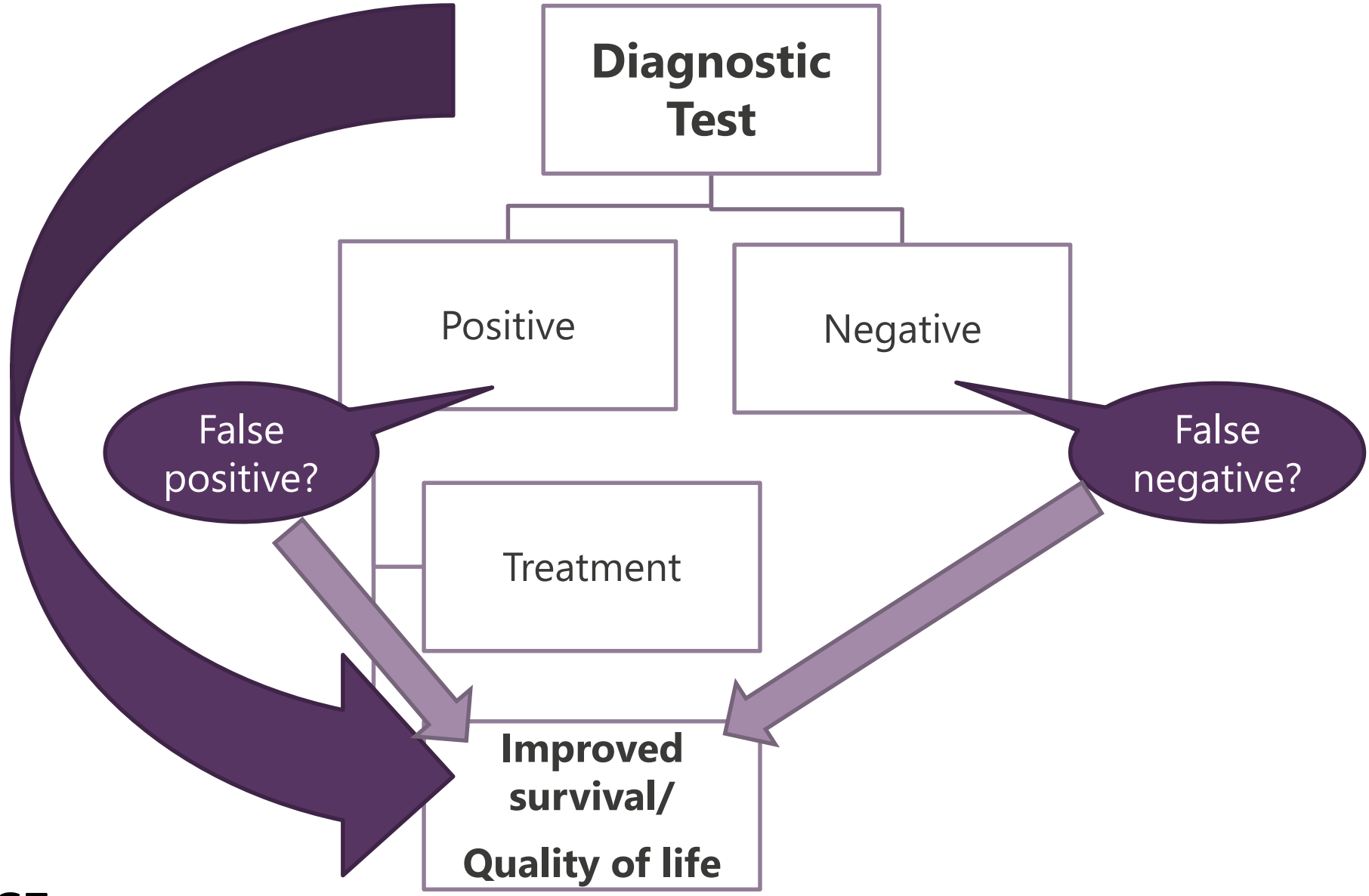
A clear and credible set of claims for which evidence can be developed that provide value to healthcare providers and users.

1. How is the condition managed in the NHS?

2. Where does my product fit in the care pathway?

3. What does my product deliver?

Understanding benefits: diagnostics



Understanding benefits: diagnostics

Patient benefits rarely arise from the diagnostic directly – they come mainly from treatments informed by the diagnostic

The treatment pathway or the range of pathways must be understood for the value of the diagnostic to be assessed

Need to know the reference test

Test side effects should be included

What makes a good value proposition?

- Think about your audience
- What represents value in healthcare systems and in particular the NHS?
  - Is your VP actually giving payers what they want?
- A value proposition aimed at NICE, healthcare commissioners and professionals differs from that a company might use for potential investors

Proving your value proposition

- Can be even harder to get the evidence to justify the claim
  - Does it work in clinical trials?
  - Does it work in clinical practice?
  - Does it contribute to more efficient use of resources?

Key elements of value proposition development

1. Describe the issue being faced [in the NHS] in relation to this indication and current clinical practice.

2. Explain how the technology in question can provide a solution to this problem.

3. Detail the clinical benefits for patients delivered by the product over and above current clinical practice.

4. Detail the resource use and cost savings for the healthcare system delivered by the product over and above current clinical practice.

5. Remember the need to provide evidence to substantiate the claims.

Are these good value propositions?

Improves quality of life for the patient and their family

Empowers patients to treat their own disease

Excellent for orthopaedic work

It's the most technologically advanced and robust system on the market

Test identifies which patients presenting with head injury have a life threatening condition requiring urgent admission enabling others to be discharged

No need for repeat surgery

Improved design has been clinically proven to enhance patient outcomes in a number of studies

Leads to earlier discharge from ICU

9 out of 10 doctors prefer to use…

Easy and convenient to use

Avoids the need for an MRI scan

The PICO framework

Defining the clinical question

Population	Usually the patients indicated in the marketing authorisation
Intervention	Technology to be appraised
Comparators	Established practice in the NHS
Outcomes	Outcomes which have an impact on: - survival - health related quality of life (HRQL)

Population

Define the target patient population as precisely as possible:

- Who is the product intended for?
- Disease
- Severity or treatment stage
- Presenting symptoms
- Genetic factors
- Other patient characteristics

Conduct your studies in the relevant target population

Population - Subgroups

- Effectiveness and cost effectiveness may differ because of some characteristic of the patients

For example:

- A companion diagnostic test may identify the subgroup of patients who will respond best
- The patient may have a different baseline risk of having a certain event

Think in advance about identifying any subgroups

Intervention

- The intervention is the actual technology (test or device) proposed by the manufacturer for a specific purpose

- I also stands for index diagnostic test

- Be precise about how it is used:
  - -in what setting?
  - -who uses it?
  - -when?

Comparator(s)

The comparator(s) is a treatment or test that is commonly used as part of current management

- There may be more than one comparator
- The comparator may be ‘best supportive care’
- Diagnostics: there can be multiple tests or variants or test sequences in common use and all would be relevant comparators

Diagnostics outcomes

Outcomes: patient focussed outcomes are particularly important, as opposed to intermediate or surrogate outcomes

e.g. a reduction in tumour size will be given less weight than evidence about clinical benefit such as improved survival or quality of life

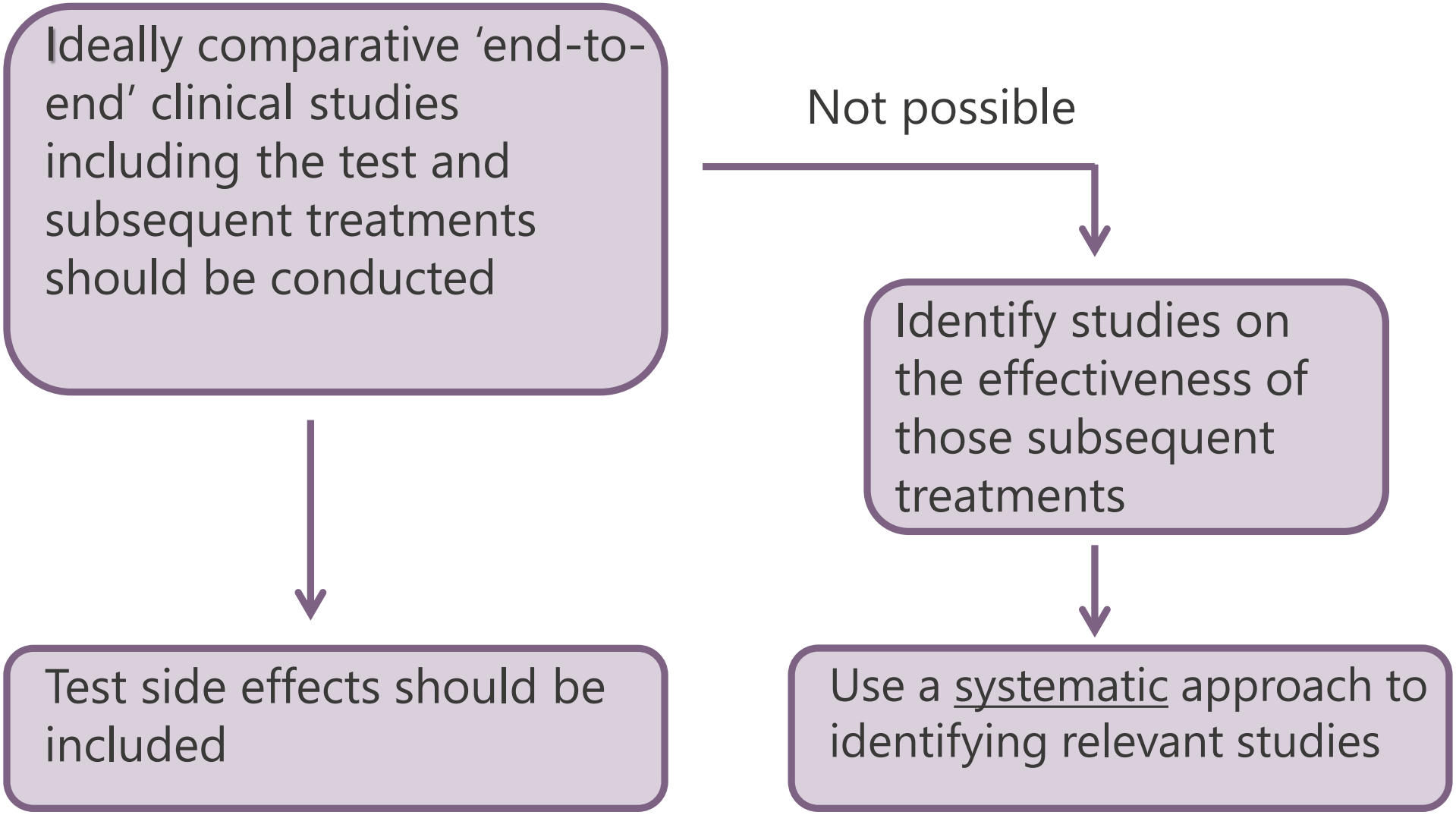
Outcomes vary depending on population

- Different prior probabilities of disease
- Test accuracy can vary in differing populations, disease stage
- Differences in impact of treatment, side effect and complications

Alternative follow-up/confirmatory tests

Cut-off point on the receiver operating characteristic (ROC) curve used.

Diagnostic tests: Outcomes data

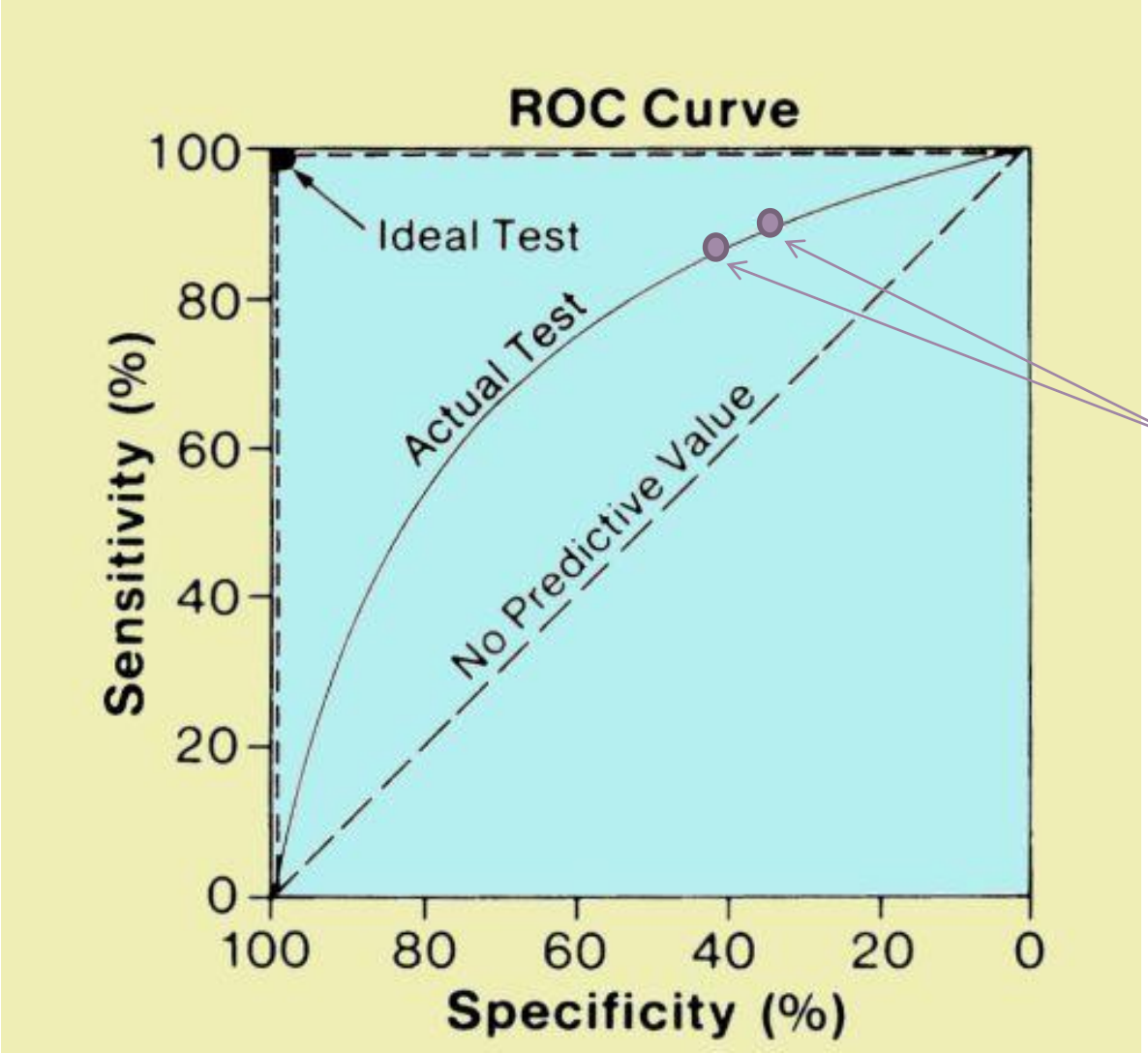


Diagnostic tests: Outcomes data

Measurements of test accuracy are necessary:

		Condition as determined by "Gold Standard"		
		Condition positive	Condition negative	
Test outcome	Test outcome positive	**True Positive**	**False Positive**	**PPV**
	Test outcome negative	**False negative**	**True Negative**	**NPV**
		Sensitivity	**Specificity**	

Diagnostic tests: Outcomes data



Cut off points

Fitting your product into the treatment pathway

What is the current pathway(s) in NHS?

- How did you obtain this information?

Your product:

- Does it replace or act as alternative to an existing technology?
- Does it add or remove a step in the pathway?
- Is it aimed at specific subgroup?

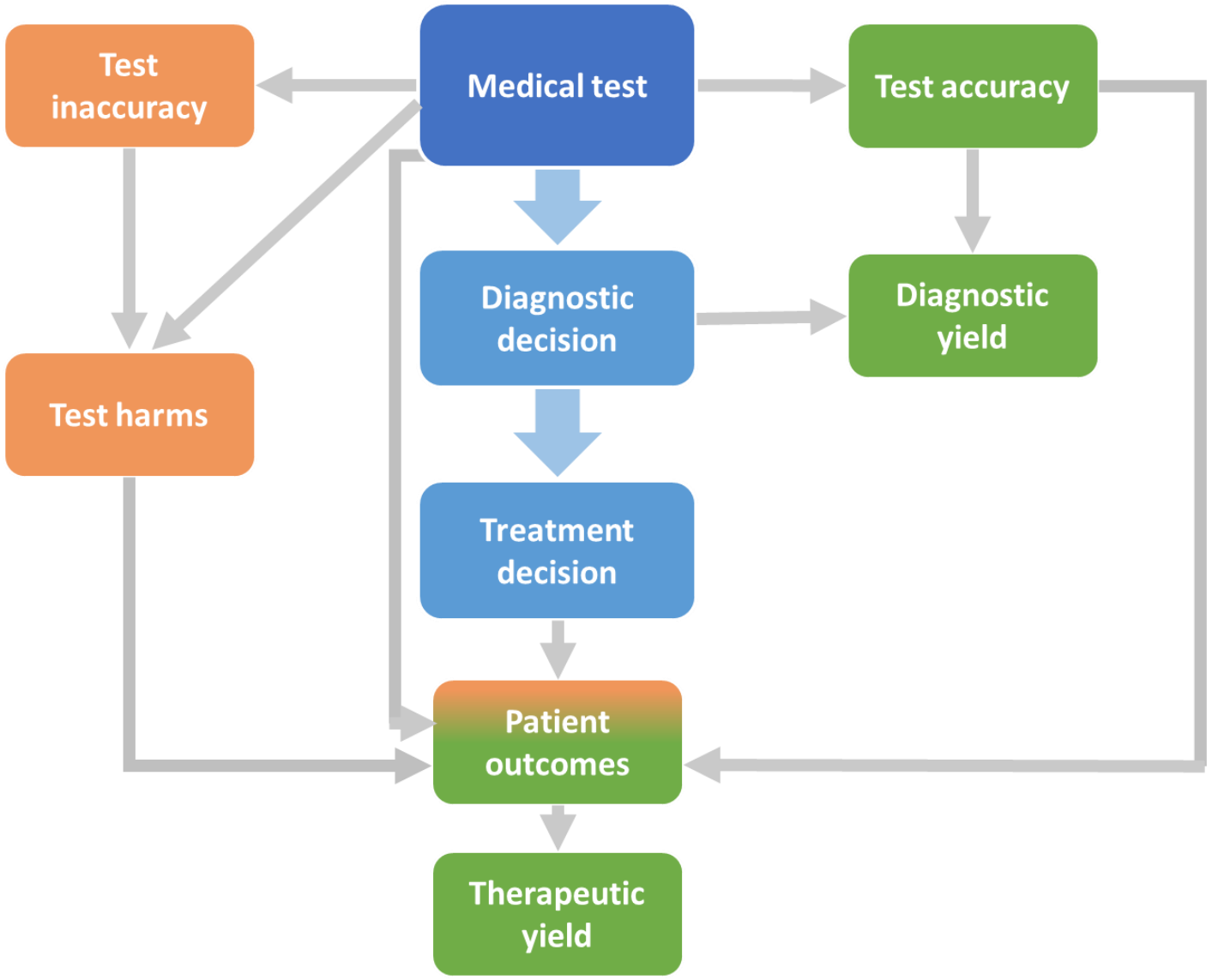
Think about how your product might fit in the pathway, and how this affects the value proposition and the evidence you need to collect to support it

How does a diagnostic test change the pathway of care?

- Usually benefits come from changes to the subsequent treatments and tests which in turn changes the outcomes for the patient and the overall costs
- The test may target treatment to those who are likely to respond best
- Patients are less likely to receive ineffective or unnecessary treatments
- Subsequent treatments, any side effects and their treatments may be avoided

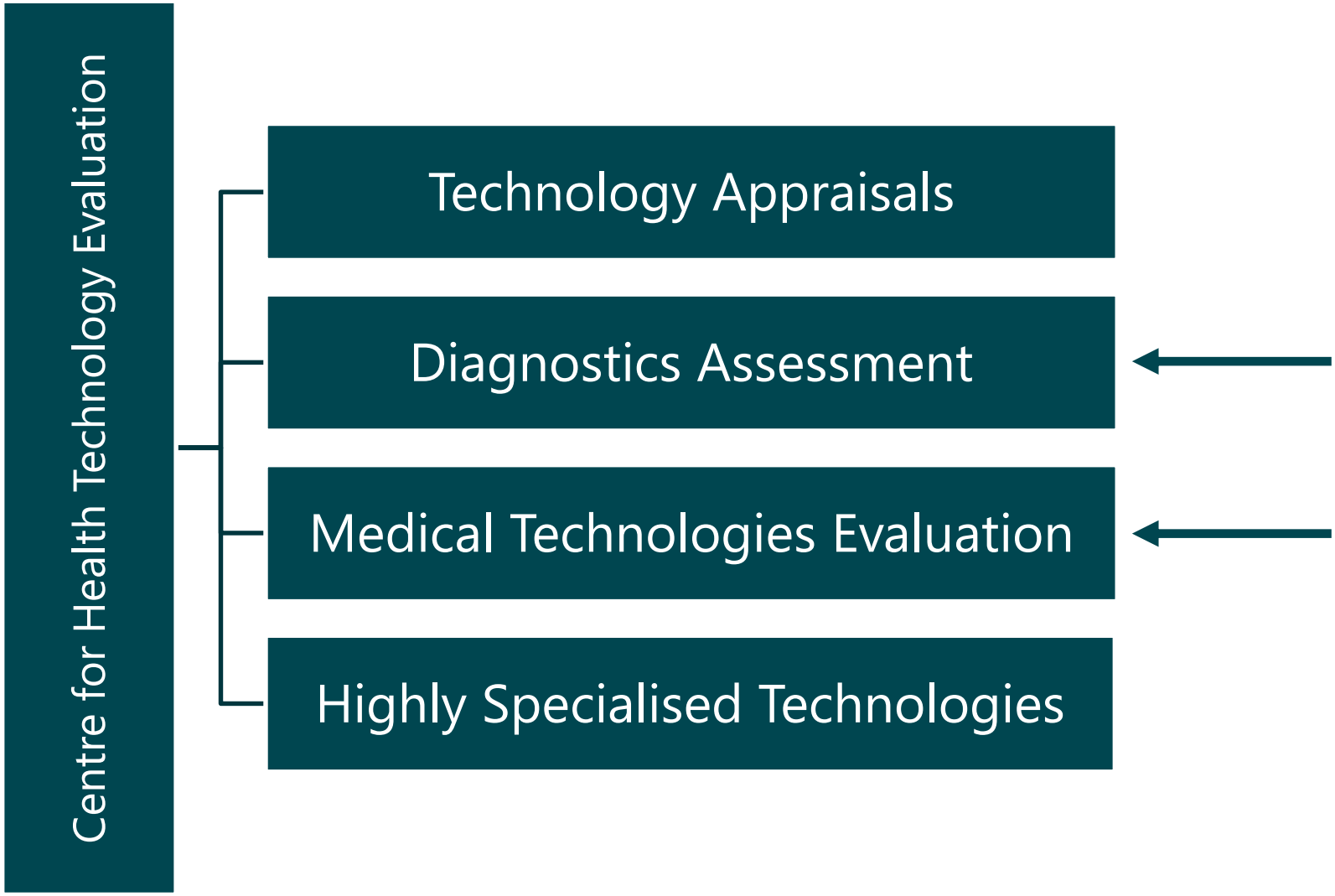
Patient benefits rarely arise from the diagnostic directly – they come mainly from treatments informed by the diagnostic

Diagnostics: consider whole treatment pathway



Programmes at NICE

NICE HTA programmes



MedTech publications

- **NICE guidance**
  - Interventional Procedures Guidance
  - Medical Technologies Guidance
  - Diagnostics Guidance
  - Technology Appraisals Guidance
  - Highly Specialised Technologies Guidance

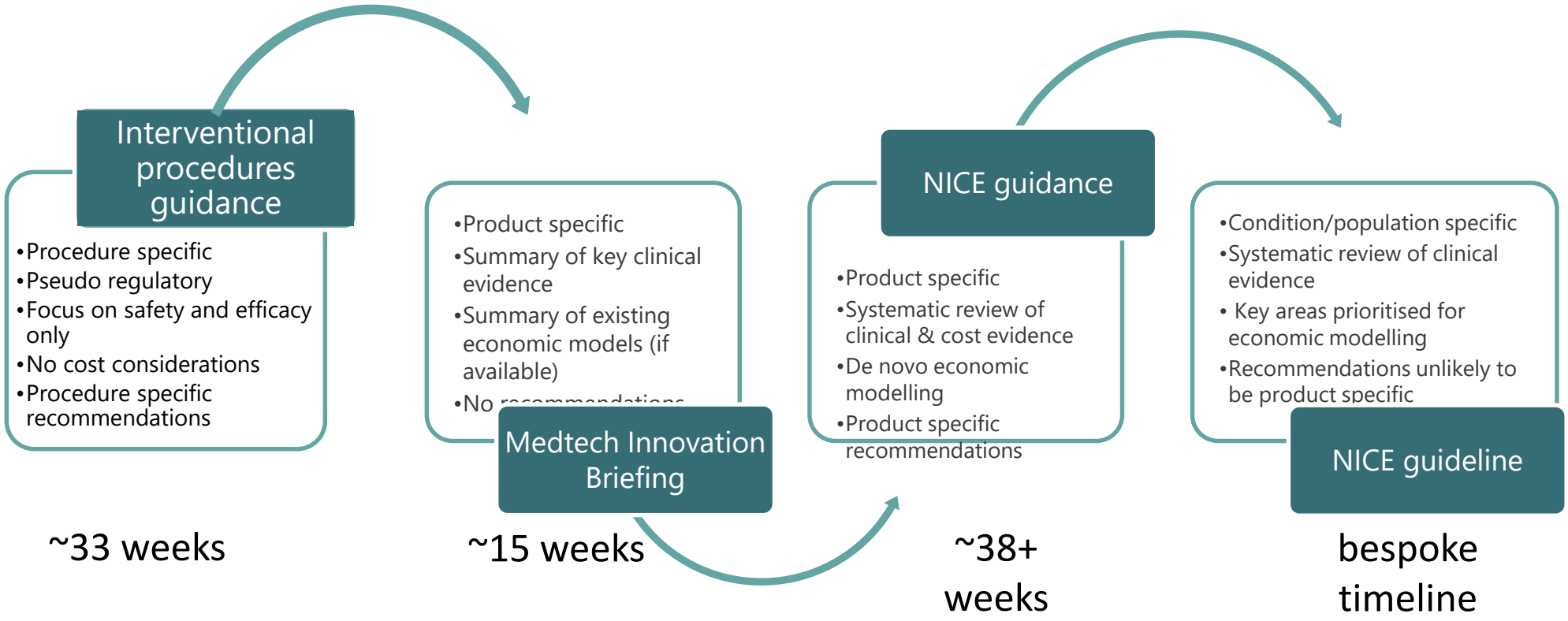
- **NICE guidelines**
  - Clinical conditions
  - Social care
  - Public health

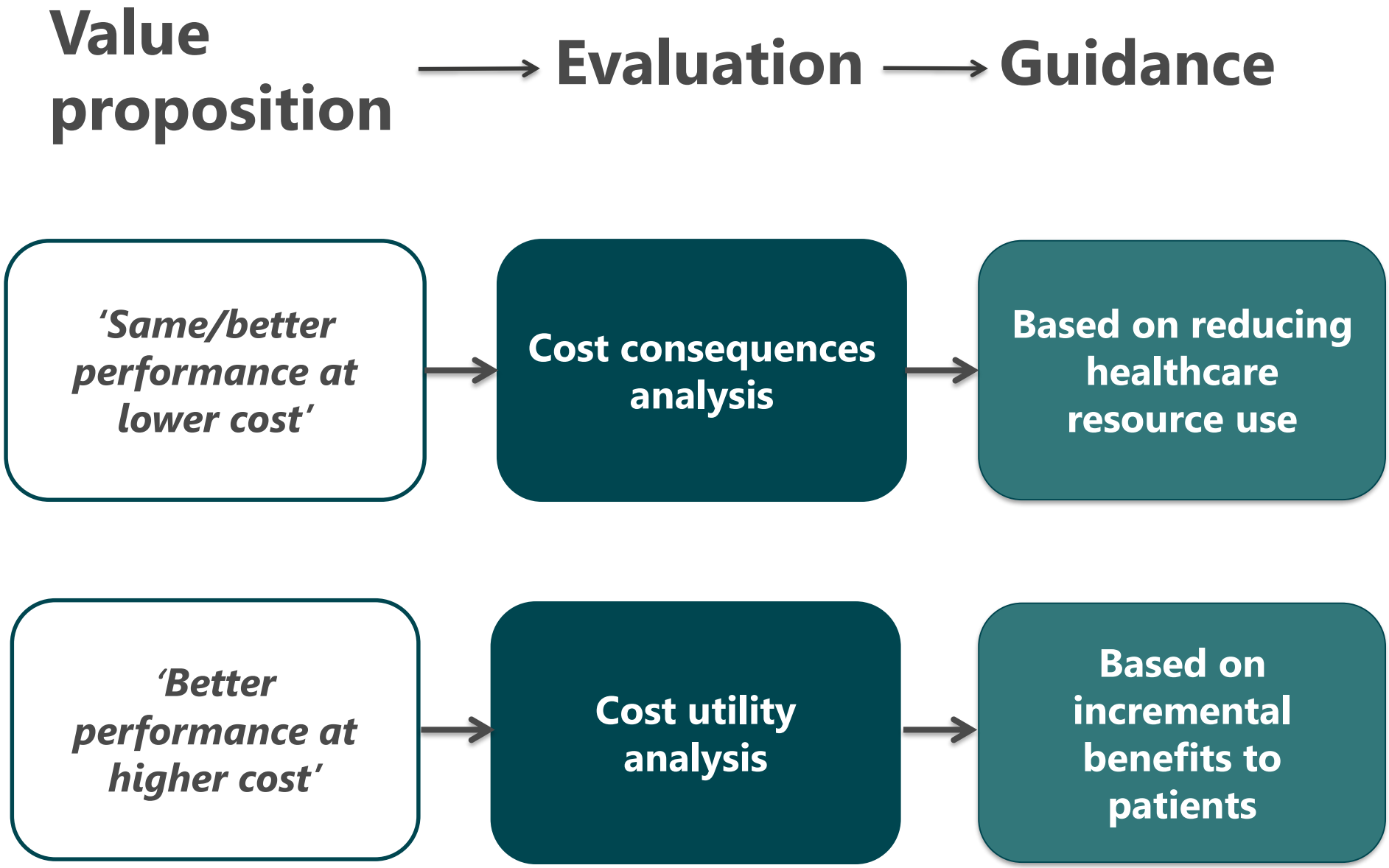
- **NICE advice**
  - Medtech innovation briefing
  - Health app briefing

Options for NICE consideration of medtech value propositions

Clinical performance	Better		Non-inferior
Cost	Higher		Less overall
Evaluation method	Cost effectiveness (QALY)		Cost consequences
NICE guidance programme	Technology Appraisals Programme (TA)	Diagnostics Assessment Programme (DAP)	Medical Technologies Evaluation Programme (MTEP)
Technologies	✓ Devices	✓ Diagnostics	✓ Devices ✓ Diagnostics

Potential journey



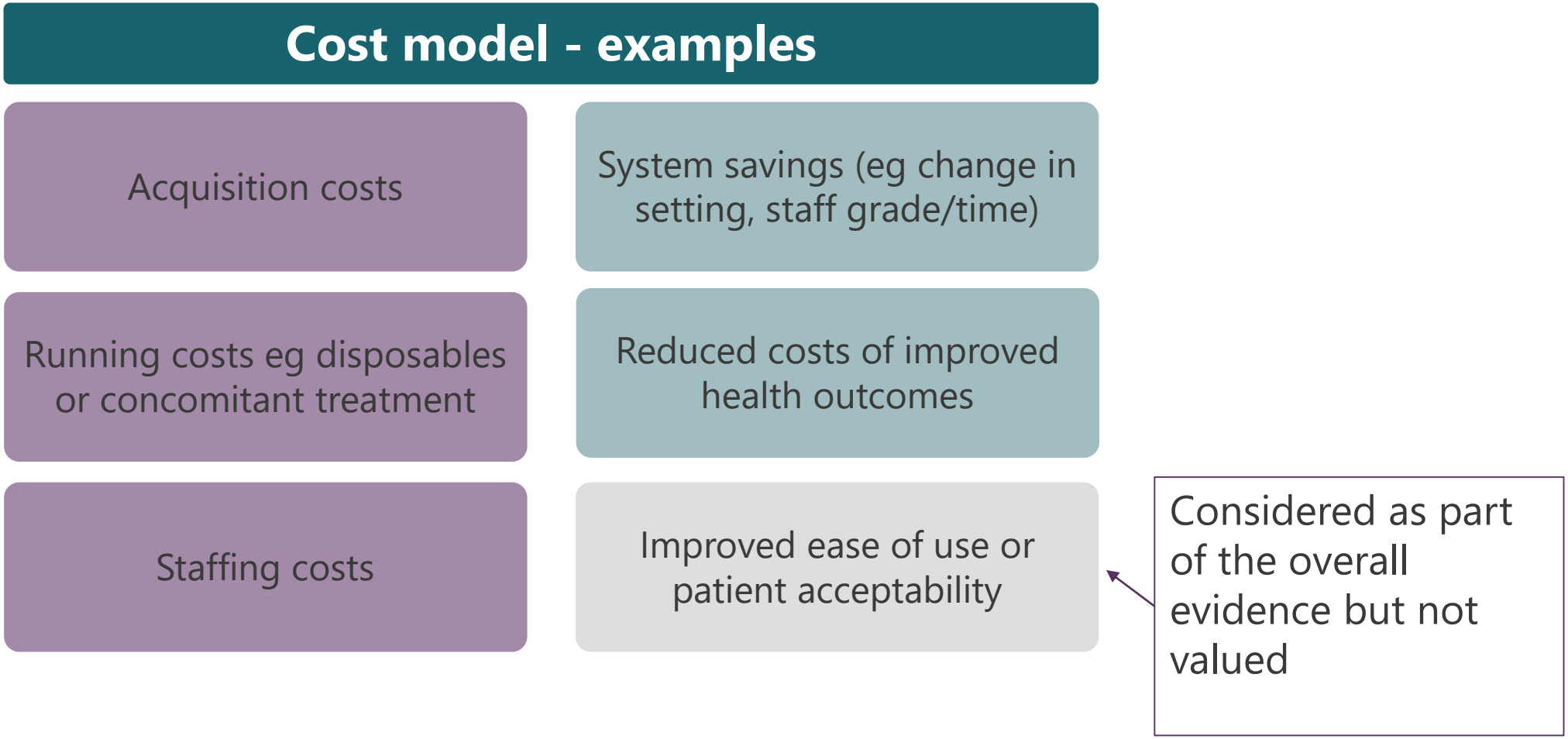

Value proposition
Evaluation
Guidance
'Same/better performance at lower cost'
Cost consequences analysis
Based on reducing healthcare resource use
'Better performance at higher cost'
Cost utility analysis
Based on incremental benefits to patients

Medical Technologies Evaluation Programme

AIMS: Identify > Evaluate > Promote adoption
Novel …. or apparently under-used techs

- Aim to identify promising technologies early
- Permissive approach to clinical evidence
- Good expert advice is vital
- "Promise" and plausibility important
- Comparison with current management
- Clinically non-inferior and no more costly
- Modelling for cost consequences
- Single technologies (products)

Medical technologies guidance: cost consequences analysis



After guidance: Adoption support

- Develop resources to support the adoption of selected NICE guidance
- Focus is on guidance where adoption barriers have been identified
- Resources provide practical support to organisations to help them put the guidance recommendations into practice
- Tools to estimate the resource impact

Medtech Innovation Briefing (MIB)

The aim of MIBs is to provide objective information on medical technologies as an aid to local decision-making by clinicians, commissioners and procurement professionals.

MIBs do

- Provide a rapid, responsive service that gives objective information on device, diagnostic and health app technologies to aid local decision-making by clinicians, managers and procurement professionals.
- Use publically available information.

MIBs do not:

- Constitute guidance from NICE
- Contain a recommendation or judgement about the technology
- Preclude guidance being developed in future

MTEP vs DAP

Medical Technologies Evaluation Programme

- Single product evaluated
- Early stage evidence
- [illegible]
- More benefit for the same cost or

Diagnostic Assessment Programme

- Multiple products evaluated
- [illegible]ted benefit
- Complex care pathways

DAP and MTEP encourage further research into promising technologies

Diagnostics Assessment Programme

Specialist programme to undertake complex assessments of diagnostic technologies

Decision making by **independent Diagnostics Advisory Committee**

Assessment of **single or multiple** technologies

No formal manufacturer submission required

Systematic review of evidence and modelling to estimate outcome benefits and **cost effectiveness** is undertaken as part of the assessment

Overview of assessment process

- Guidance **topic referred** to DAP from MTEP
- **Scoping**
- **Assessment** of evidence by external assessment group
- **Draft recommendations** developed by DAC
- Draft recommendations released for **public consultation**
- DAC consider feedback and develop **final recommendations**
- Final recommendations **approved by GE** for publication
- Guidance released for **resolution** period
- **Guidance published**

NICE Guidelines

- Clinical conditions
- Social care
- Public health

- **Systematic review of all relevant evidence**
- **Recommendations made by committee**
- **Very unlikely to recommend specific products**
- **Economic modelling on prioritised areas**
- **Evidence needs to be well developed**
- **Bespoke development timelines**

Medtech Publications

Not mandatory- except TA/HST

Not needed for use in NHS. Decisions can be made

- Locally
- Regionally (e.g. CCGs)
- Nationally (e.g. NHSE)

Topics identified in many ways:

- Core library of conditions, diseases, population groups
- Referrals from other organisations (e.g. NHSE)
- Horizon scanning (e.g. HealthTechConnect, UK pharmascan, NIHR innovation observatory)
- Notifications from clinicians/companies

NICE's selection considerations

What are the benefits compared with current management?

Patient outcomes/experience

Use of resources- facilities, staff, tests

Do the benefits matter?

Will it change how patients are managed?

Are the benefits meaningful to patients/staff/carers

What does it cost?

Is evidence available?

Other potential adoption mechanisms into the NHS

- Commissioning through Evaluation
- Individual Clinical Commissioning Group decisions

Commissioning through Evaluation

- Limited programme for access to treatments that are not currently funded by the NHS but show significant promise for the future
- Collection of clinical and patient experience data within a formal evaluation programme
- Phase 1
  - Patients are recruited, with NICE assistance to determine the scope of the scheme
- Phase 2
  - Analysis phase of varying length (usually not longer than 24 months)
- Once data are available, NHS England reviews the published policy

NICE programmes and PoC tests for AMR

At the moment, the same methodology applies

- Establish the current treatment pathway
- Describe effects on downstream clinical outcomes
- Discuss clinical acceptability
- Determine QALYs and subsequent ICERs
  - Can be very difficult to develop models and generate QALYs/ICERs

DAP committee flexibility

- - Purpose of NICE is to ensure good value for the NHS

Point of care tests – questions to think about

- What does Point of Care mean?
- What is the relevant setting?
- Who should be making the decision to request a test?
- Who should be conducting the test?
- How long does the test process take?
- How accurate is the test?
- What is the evidence that the result affects the treatment pathway?

AMR PoC tests

Think in terms of the value proposition:

- Accuracy compared to established tests
- Speed

Very difficult to develop linked evidence

- Potentially for antimicrobial prescribing reduction
- Not for AMR reduction

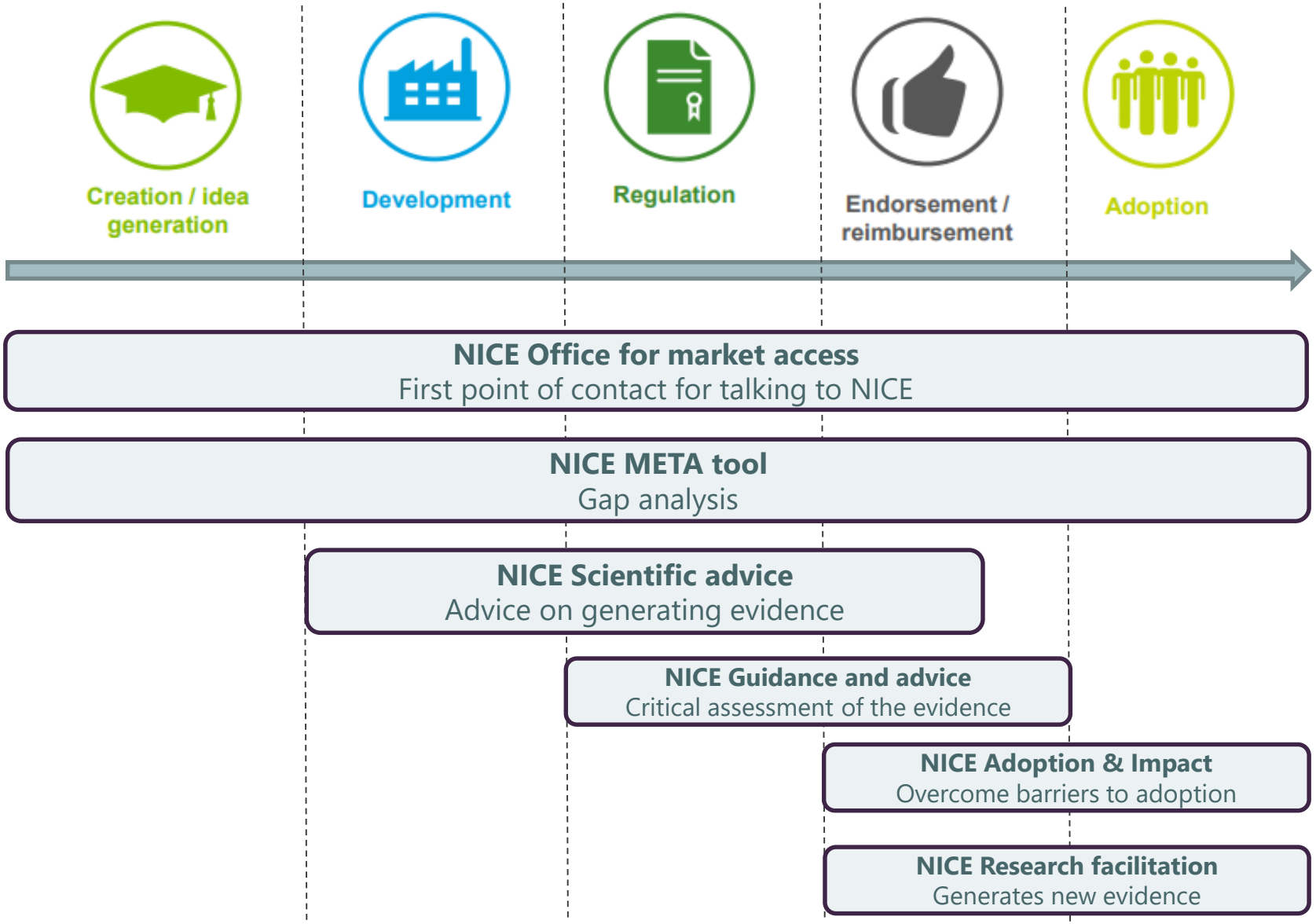
Adoption issues:

- Space
- Training of staff
- Credibility

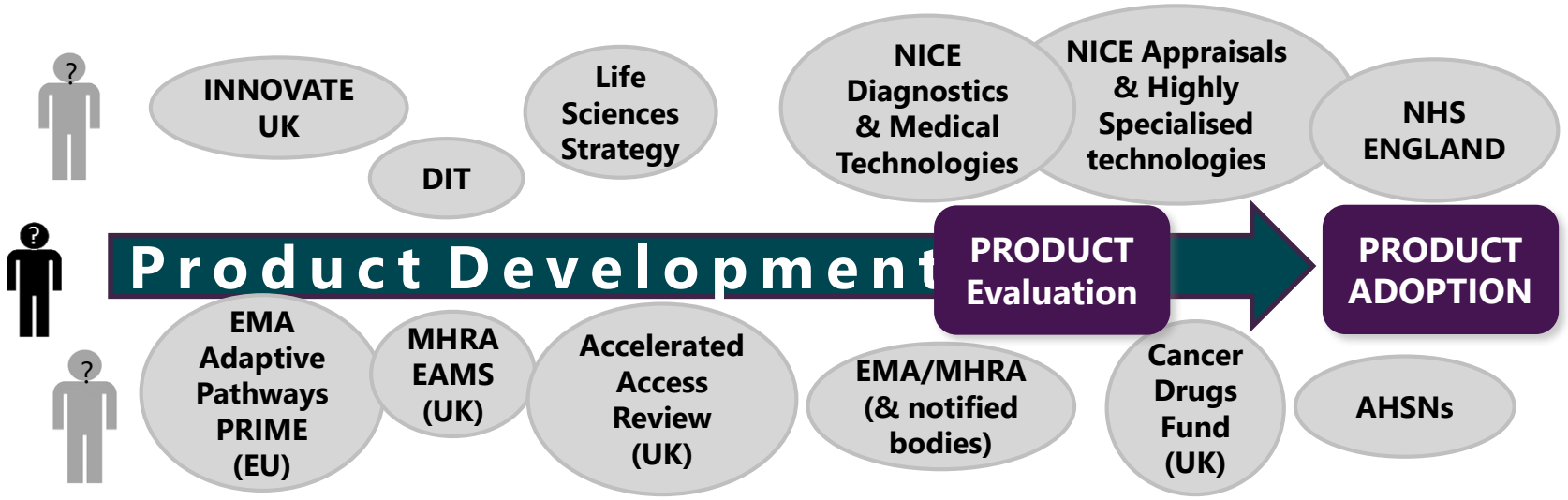
PoC is only meaningful if it affects the treatment pathway

Engaging with NICE

NICE's 'offer'


Creation / idea generation
Development
Regulation
Endorsement / reimbursement
Adoption
NICE Office for market access
First point of contact for talking to NICE
NICE META tool
Gap analysis
NICE Scientific advice
Advice on generating evidence
NICE Guidance and advice
Critical assessment of the evidence
NICE Adoption & Impact
Overcome barriers to adoption
NICE Research facilitation
Generates new evidence

The changing landscape



Exciting times!.....

Very strong pipelines of products with potential for major patient benefits

Patients and healthcare systems need access to clinically and cost effective products as quickly as possible

Personalised/precision medicine becoming a reality...

Challenges:

High cost of some products

Timely patient access while the evidence is still emerging

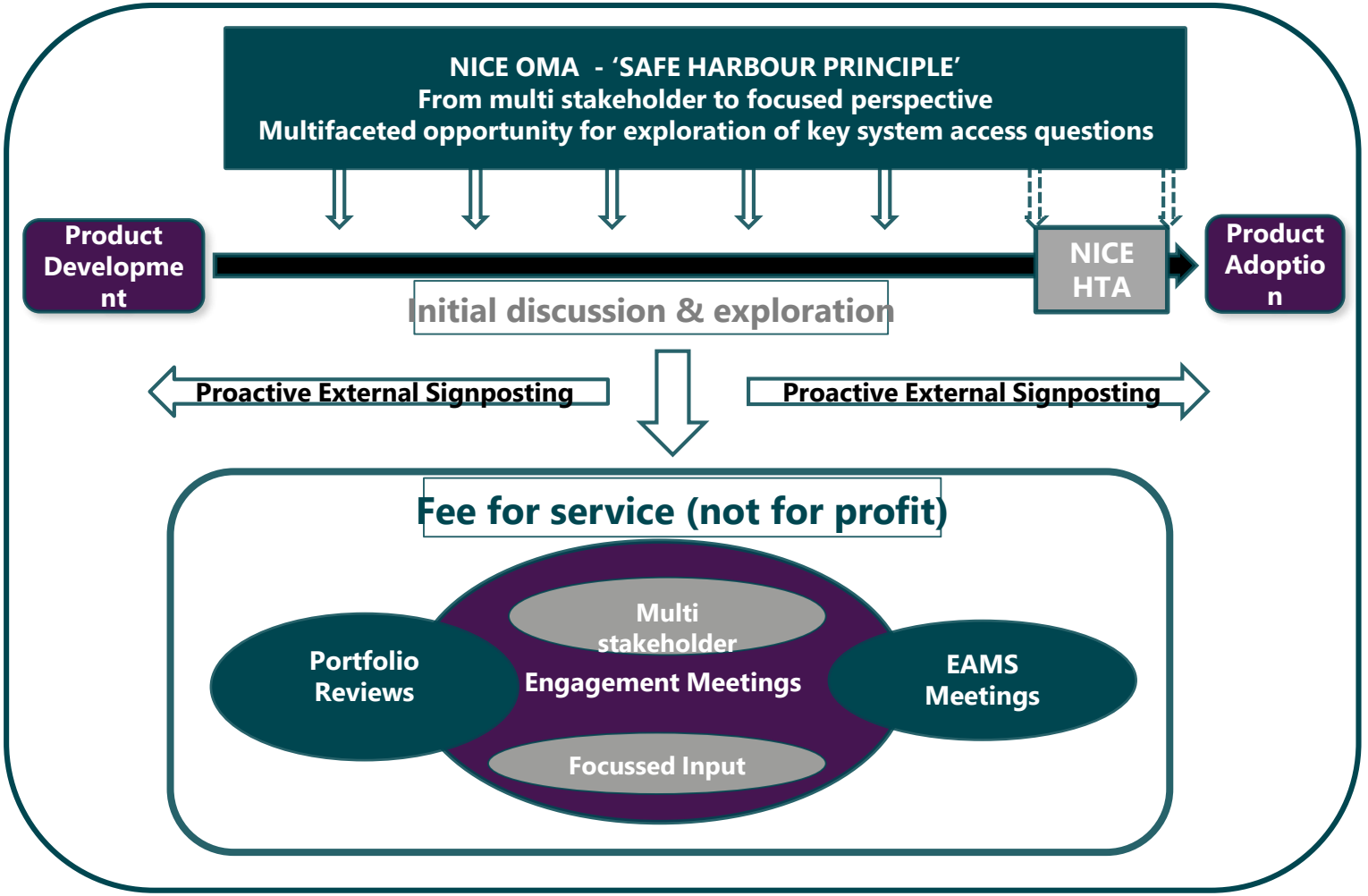
New initiatives in the landscape

Effective engagement necessary to address challenges:

The Office for Market Access

NICE Scientific Advice

NICE Office for Market Access (OMA)



- Covers all life sciences products:
  - Pharmaceuticals, biopharmaceuticals, medical devices, diagnostics & digital(if patient benefit)
- Tailored engagement and expert advice to help companies optimise the journey through NICE
- OMA provides opportunities to engage with NICE at any stage in the product development to adoption pathway
- Every company's needs are different, so we offer bespoke services tailored to requirements
  - Fees are charged on a not-for-profit basis (varying in scale to reflect the resources required).

NICE Scientific Advice

Advice on prospective clinical and economic development plans, which…

Helps you generate robust evidence to demonstrate value, which…

Can be used for future evaluations or discussions with payers / commissioners

Why seek Scientific Advice?

Understand the perspective of decision makers

Understand pros and cons of different trial /study options

Maximise relevance of trial programme outputs

Explore alternative strategies to address data gaps

Integrate cost effectiveness considerations into early decision making

De-risking strategy

International Knowledge Transfer Services

- These services offer advice, support and insight into NICE processes. By sharing our experiences we can help you to:
  - ✓ assess your healthcare programmes
  - ✓ develop your own methods, processes and strategies
  - ✓ identify areas for risk assessment and review
  - ✓ develop new healthcare strategies
- We also offer bespoke services including seminars workshops, capability building…
- Fee for service on cost recovery basis

- **www.nice.org.uk/about/what-we-do/international-services/knowledge-transfer**

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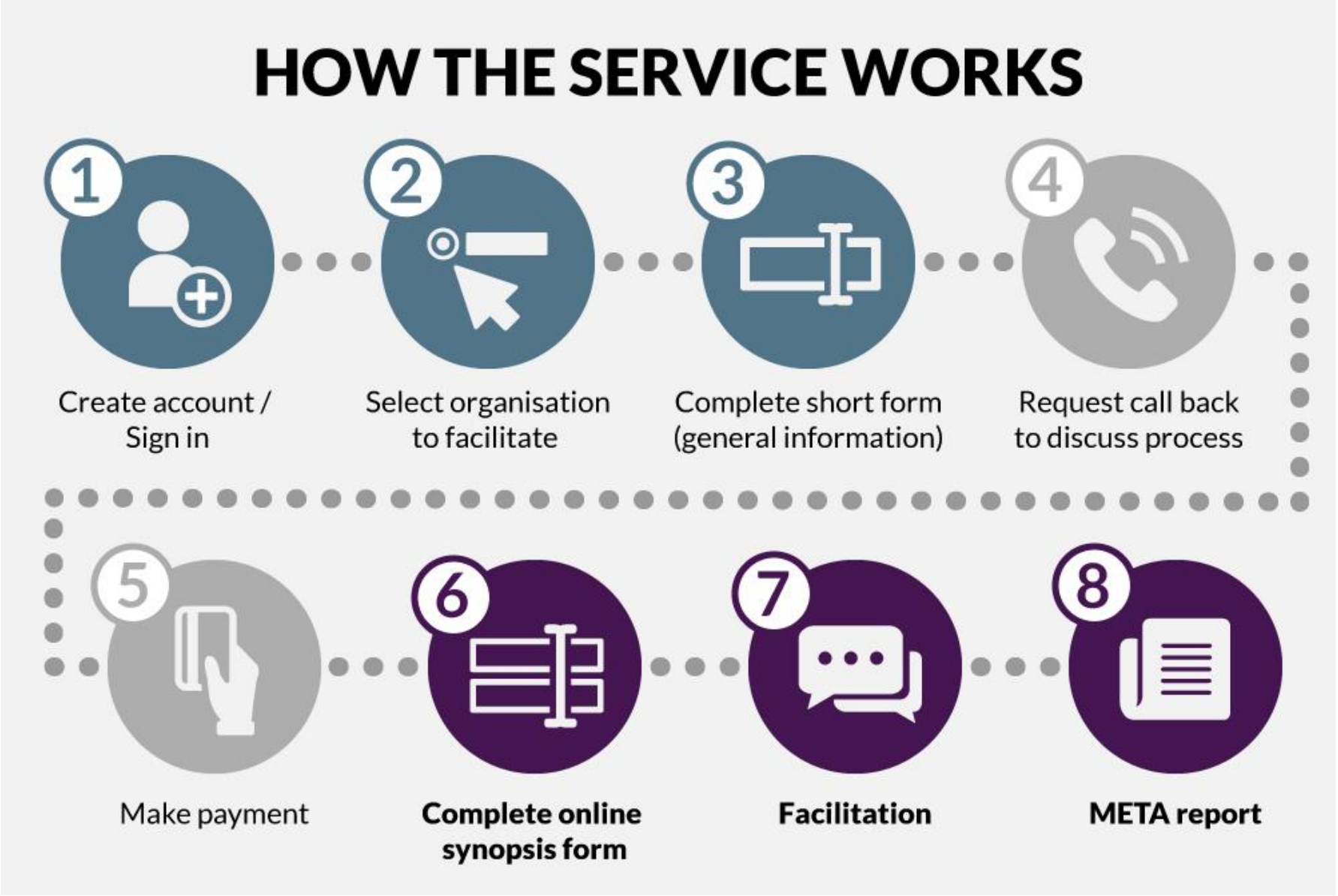
The META tool

In collaboration with GMAHSN and their partner TRUSTECH

GREATER MANCHESTER ACADEMIC HEALTH SCIENCE NETWORK

TRUSTECH
The North West NHS Innovation Service


HOW THE SERVICE WORKS
1
Create account / Sign in
2
Select organisation to facilitate
3
Complete short form (general information)
4
Request call back to discuss process
5
Make payment
6
Complete online synopsis form
7
Facilitation
8
META report

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Any questions?

Additional slides

Useful Links

- NHS England antimicrobial stewardship
- Notify a medical technology to NICE
- NICE Diagnostics Assessment Programme
- Diagnostics Assessment Programme manual
- Technology Appraisals Programme
- 2013 Guide to the methods of technology appraisal
- NHS Commissioning through Evaluation
- Scientific Advice Programme
- META tool
- HealthTech Connect

Useful resources to help with trial design

CAMPUS database (http://campus.ecrin.org/)

ECRIN MD outcomes measure database (http://ecrin.org/tools/medical-device)

Ideal, Development, Exploration, Assessment, Long-term follow-up (IDEAL) collaboration (www.ideal-collaboration.net)

National Institute for Health Research (NIHR) Clinical Trials Toolkit http://www.ct-toolkit.ac.uk/

European Clinical Research Infrastructure Network (www.ecrin.org)

Assessment evidence requirements

What data do you need?

Regulator

Product safety: laboratory testing with clinical trial data for devices with greatest risk

Evidence of efficacy: does the device meet its intended purpose? (not necessarily from comparative studies)

HTA

Evidence on clinical effectiveness (compared to established practice): trials, evidence synthesis

Evidence on cost effectiveness:

trials, modelling

Evidence on relative safety/adverse events

Trueman P et al 2011

Evidence- how much is needed?

It depends.....

Uncertainties about **the disease** and how it is best managed

Uncertainties about **the technology** and how it works

Uncertainties about **the benefits** and what value they have

Etc....

High uncertainty = more evidence

Low uncertainty = low evidence

Evidence requirements

Varies by programme, but in general….

Any evidence from any country

No design/quality thresholds

- Published and in-press research (academic/commercial in confidence)
- Unpublished data
- Real world data, register data, audits, post market surveillance
- Forthcoming trial results

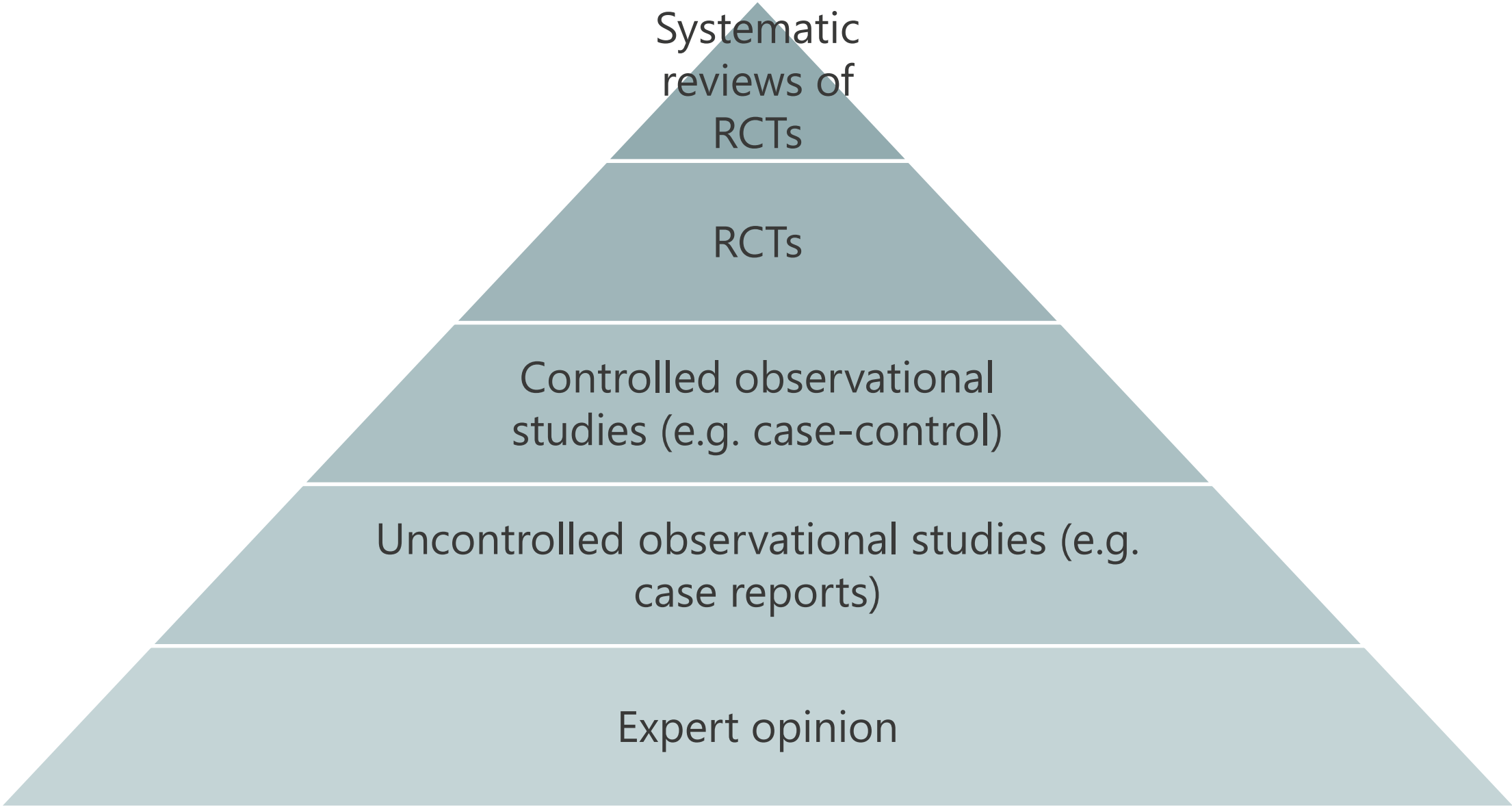
Each technology/potential benefit assessed on case by case basis

Evidence considerations

The ideal evidence would be a good quality 'end-to-end' study – follows patients from testing, through treatment, to final outcomes

- Typically not available for diagnostics
- Search for data on test accuracy, direct outcomes from the test, indirect health outcomes from the test result, and costs
- Identified evidence can then be combined through a **linked evidence approach**

Evidence hierarchy



Evidence on devices and diagnostics from research/clinical studies…

… typically sparse and poor:

- Little regulatory demand (unlike drugs)
- Many manufacturers inexperienced
- RCTs challenging on devices
- Evaluation often early in trajectory

Size: Studies with larger numbers of patients will usually be preferred as estimates of benefits and harms will be more accurate

Duration: Studies should have sufficient follow up to capture final outcomes where possible

e.g. very important for prognostic tests

Discussion with stakeholders for market access

Routes for engagement with stakeholders

- Budget impact test and managed implementation
- Patient access support liaison unit (PASLU)
- Managed access agreements (MAA)
- Office for market access (OMA)
- Scientific Advice

Features of a good Managed Access Agreement

- simple,
- reproducible,
- has the capacity to be consistently applied
- will not unduly add to the administrative burden of the process for NICE or its stakeholders

CDF decision consists of 2 key elements:

- Data Collection Arrangement
- CDF Commercial Agreement, determining the cost of the drug during the managed access period; cost of the drug reflects the decision uncertainty.

CDF: Plausible potential but evidence not robust enough to be considered for routine commissioning

…an example – the Cancer Drugs Fund (CDF)

Budget impact test and managed implementation

Reconcile the roles of **NICE** and **NHS England**

→ Clinical & cost effectiveness → Effective service delivery

Flexibility in the adoption of cost-effective, high budget impact technologies

- Balance value and affordability

Budget impact threshold: £20m/year in first 3 years	
Negotiate access arrangements	Variation to the 90 day funding direction

Cost effectiveness vs. Resource impact

Cost-utility analysis	Cost-impact analysis
Is it **value** for money?	How much it will **cost**?
Cost per health gain for **one** (hypothetical) patient	Total cost for **England**
Used to **inform** recommendations	Used for **planning and implementation** of recommendations
Lifetime time horizon	Short time horizon (**1 to 5 years**)

Budget impact and NICE decisions

- A high budget impact will mean that the NICE committee will want to be very confident, i.e. more certain that an intervention is cost effective

- The NICE committee cannot decide not to recommend something just because it has a high budget impact

The decision maker…

Guidance Executive will consider a request from NHS England to vary the timescale for the funding requirement, taking into account whether:

- the budget impact test been met;
- all reasonable opportunities for reaching a commercial agreement been pursued;
- the request is in proportion with the magnitude of the budget impact;
- the request takes account of the severity and acuity of the condition to which the guidance relates;
- consideration has been given to NHS England's and NICE's duties under equalities legislation;
- an interim commissioning policy been developed to provide phased funding for and access to the technology during the extended funding variation period.

Managed access agreements

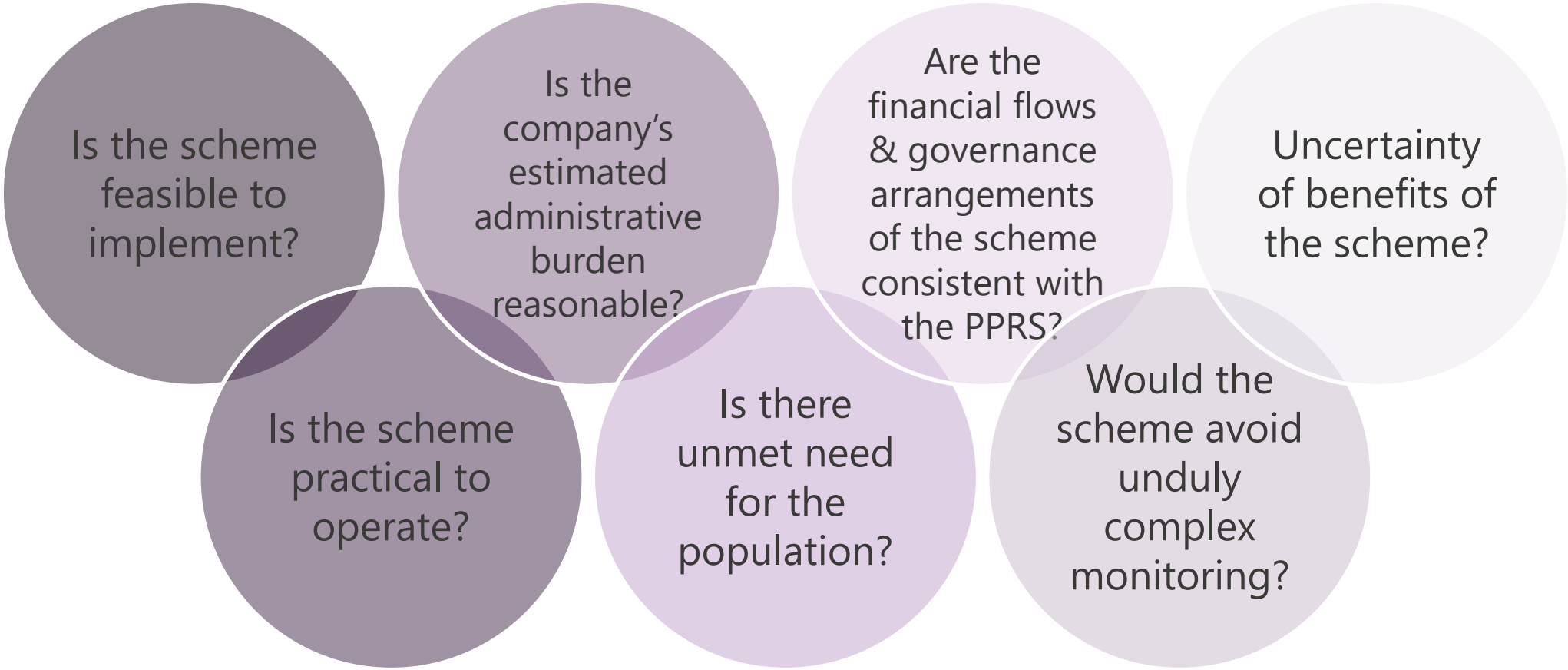
Commercial and Managed Access Programme

- Responsible for managed access activities including CDF and PASLU
- Support commercial engagement between companies and NHS England when a CAA or PAS is required to address specific uncertainties within a topic
- Commercial dialogue can be conducted:
  - before formal invitation to participate in the appraisal (for example during scoping)
  - at the decision problem meeting
  - on receipt of the evidence submission
  - at clarification
  - during technical report consultation
  - during ACD consultation.

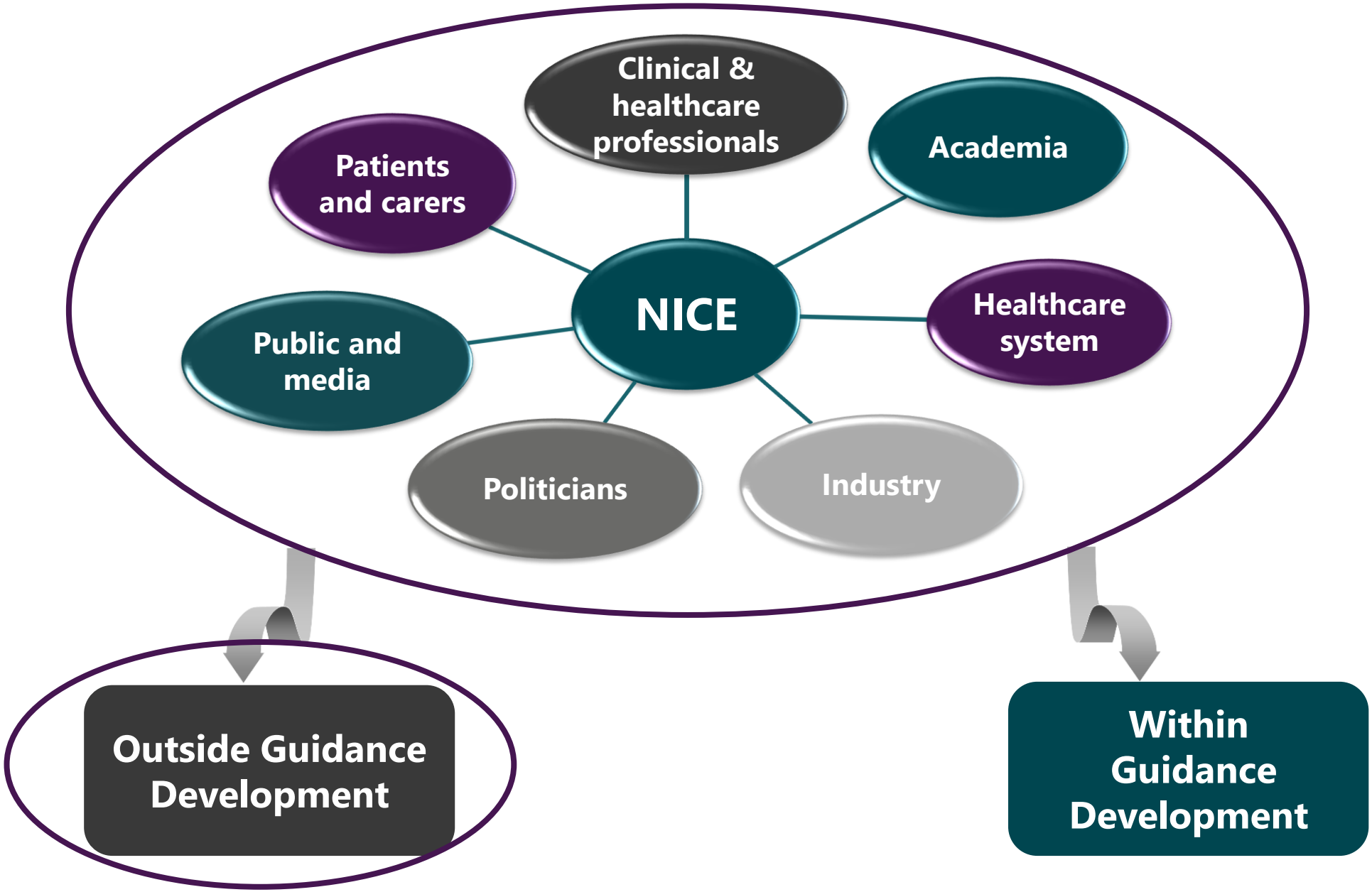
Managed Access Agreements

- A proposal that addresses a significant uncertainty
- Fixed duration, and agreement for what happens next
- Defined starting and stopping criteria
- Data collection proposal
- Financial risk management
- Patient and clinician involvement
- Time limited
- Agreed with stakeholders

Issues for consideration



More information on engaging with NICE


Clinical & healthcare professionals
Patients and carers
Academia
NICE
Public and media
Healthcare system
Politicians
Industry
Outside Guidance Development
Within Guidance Development

OMA engagement meetings under safe-harbour principles

Supported by rules of engagement to ensure a broad, open and free flowing discussion within a confidential framework

Collaborative event, including participation from a range of stakeholders

Designed to help companies deliver a market access plan that is patient & healthcare system focussed.

Multi-stakeholder engagement meetings

- *"Very interesting and positive experience, it was unusual and valuable it is to be included in discussions at this early stage"* - Patient organisation
- *"Valuable opportunity to have early discussions which enable the company to select the most feasible path forward to open up access to patients as early as possible. There was breadth and depth of relevant stakeholder input"* - Company

NICE EAMS meetings

- *"The session increased our knowledge and understanding"* - Company
- *"Useful to gain understanding of the appraisal process from a NICE perspective"* - Company

Focused engagements meetings

- *"A perfectly organized and held meeting. All input was very helpful to us. I am very impressed with the friendly, open and transparent NICE experience you gave us"* – Company
- *Extremely interesting and really enjoyable… highlight was that the meeting felt bespoke to us, it was very evident that you worked hard to understood our needs and the engagement reflected this… the meeting was conducted in a very positive and collaborative atmosphere which enabled us to ask our questions in an open and transparent way."* - Company

We are thinking about developing a managed access scheme for the UK to get our product to patients as soon as possible?

How should we optimize our value proposition ?

What are the potential routes our product might follow through NICE?

NICE Office for Market Access

We would like our company to learn more how NICE can help us?

How does our current thinking on market access sit with NICE /healthcare landscape partners ?

Our company develops products for orphan diseases, conventional approaches to evidence generation do not always work, what does NICE think about it?

We are discussing our registration package with the FDA this month, do we need to talk to EMA, NICE and other agencies?

NICE Scientific Advice

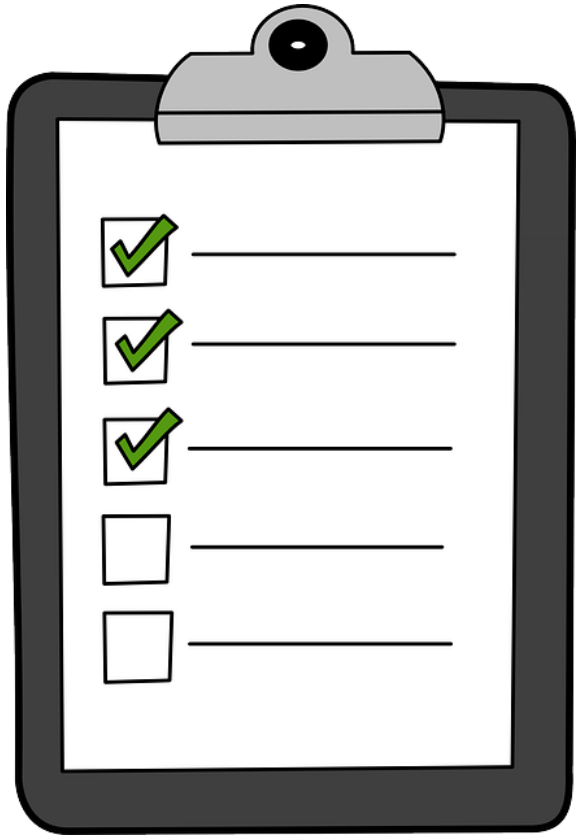
Where can I learn about NICE methods for product evaluation?

We want to discuss our product with MHRA, Should we also talk to NICE?

We are developing a life-saving gene therapy, Should we talk to NICE?

We are working on a health economics model for a product, can we discuss it with NICE?

META stages



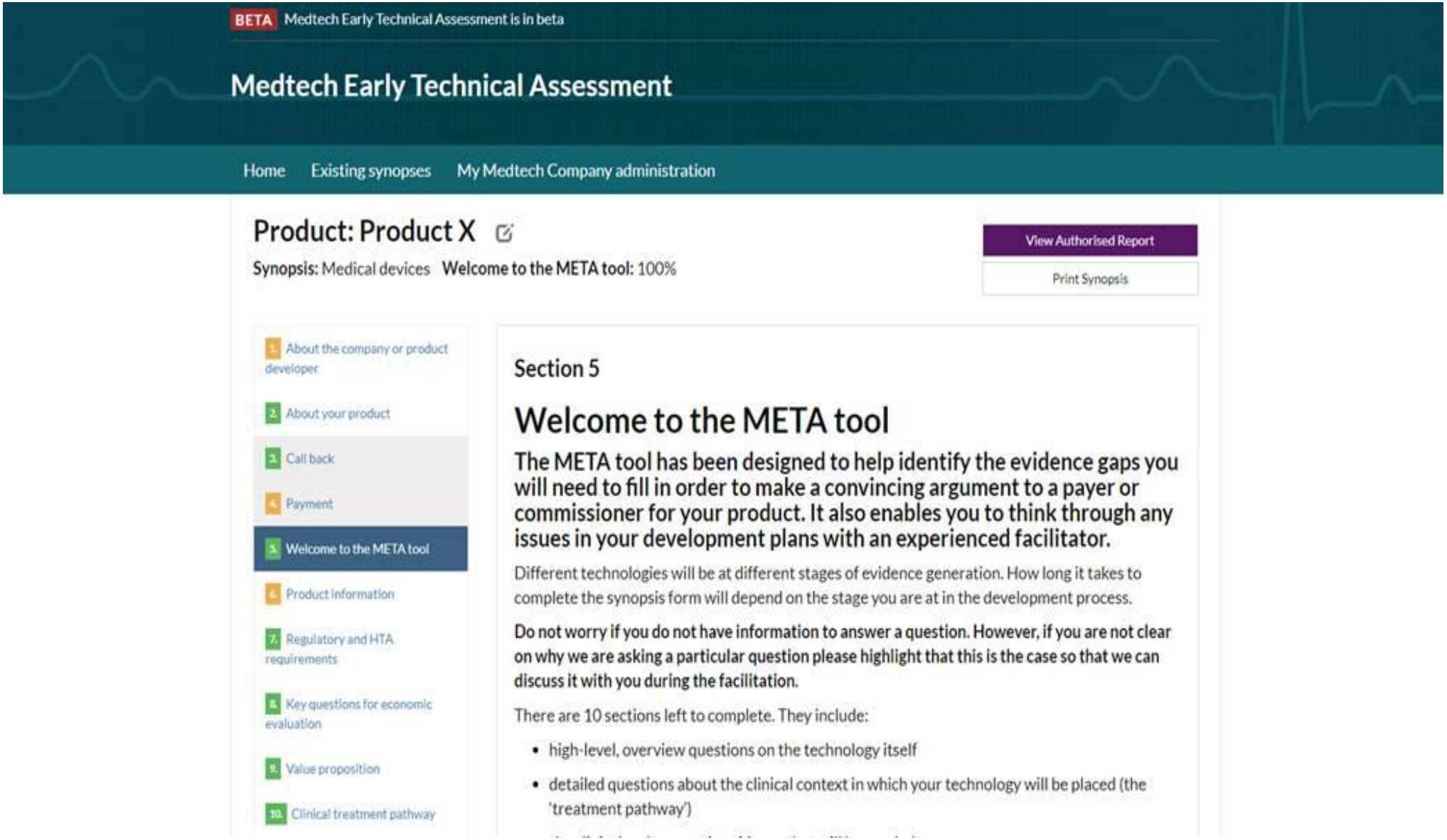
Company completes synopsis form

Facilitator reviews form and identifies any specific areas to focus on during session

90 – 120 minute guided facilitated gap analysis where company reflects on the strength of their value proposition, supporting evidence and level of preparedness for evaluation

Production of concise gap analysis report

Overview of META



The META report

- Concise!
  - A couple of pages
  - Summarises the outcomes of the discussion
  - Record areas of strengths and weaknesses in the client's value proposition and supporting evidence base
  - Record of potential next steps

Provides a gap analysis

What META is not designed for

- A META tool report is **not** meant to:
  - Provide advice
  - Act as an action plan
  - Endorse the product for potential investors

The META Report